

293. As set forth above, Immunex's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

N. The Johnson & Johnson Group (J&J, Centocor and Ortho)

294. The Johnson & Johnson Group has engaged in an ongoing deliberate scheme to inflate AWPs and to market the spread to increase the sales of its products. For example, the federal investigations have documented fraudulently inflated AWPs reported for epoetin alfa (sold by J&J as Procrit®). J&J is identified in various annual *Red Book* publications as one of two sources for epoetin alfa. The other source for epoetin alfa is Defendant Amgen.⁸

295. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services. These massive federal expenditures for epoetin alfa, caused by the J&J Group and Amgen's AWP scheme as well as the inflated cost to members of the Class, are even more outrageous given the fact that the research and development of epoetin alpha was originally underwritten by grants from the federal government.⁹

296. By way of further example, the J&J Group has deliberately overstated and continues to overstate the AWP for Remicade®. The published AWP for Remicade® continued to increase each year during the class period. For example, the AWP was listed as \$611.33 for a 100 mg vial of Remicade® as of November 1999, and rose to \$665.65 when listed in the 2001 edition of the *Red Book*. At the same time, J&J deliberately marketed and promoted the sale of Remicade® to physicians based on the availability of inflated payments

⁸ Amgen markets epoetin alfa for use in the treatment of dialysis patients while the right to market epoetin alfa for all other uses is licensed to Defendant J&J.

⁹ Epogen® and Procrit® are based on different uses of a patented process technology developed at Columbia University with support from grants from the NIH. Columbia licensed their technology to Amgen for Epogen® and to Johnson & Johnson for Procrit®. *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected*, Department Of Health And Human Services National Institutes Of Health, July 2001.

made by Medicare, assuring them that they would make a significant profit from the purchase of Remicade® as a result of the spread between the actual price to physicians and reimbursement based on the published AWP.

297. The J&J Group created promotional materials and worksheets to allow them to market the spread between the published AWP and the actual selling price to doctors. For example, a publication accessible through Defendants' web sites entitled "Office-Based Infusion Guide" demonstrates Defendants' aggressive marketing of this spread, specifically noting that, "[d]epending on reimbursement, office-based infusion may provide a financial impact to a physician's practice." Moreover, the "Financial Analysis" section of the guide includes a "REMICADE® (infliximab) Financial Impact Worksheet," which enables doctors see in actual dollars how much additional revenue the use of Remicade® would bring to their practice.

298. As set forth above, the J&J Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

O. The Pharmacia Group (Pharmacia and P&U)

299. The Pharmacia Group has engaged in an ongoing deliberate scheme to inflate AWPs. According to one member of the Congressional Ways and Means Committee:

The evidence . . . shows that Pharmacia & Upjohn has knowingly and deliberately inflated their representations of the average wholesale price ("AWP"), wholesale acquisition cost ("WAC") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers.

....

These practices must stop and these companies must return the money that is owed to the public because of their abusive practices.

See Extension of Remarks of U.S. Representative Pete Stark in the House of Representatives, October 3, 2000.

300. During its investigation, the government uncovered specific instances of fraud by The Pharmacia Group. For example, by letter dated May 25, 2000 to the HCFA Administrator, the Chairman of the Commerce Committee revealed that:

[I]n 1998, Pharmacia-Upjohn's Bleomycin had an AWP of \$309.98, but health care providers could purchase it for \$154.85. In 1997, Pharmacia-Upjohn's Vincasar could be purchased for \$7.50, while the AWP was a staggering \$741.50.

See letter dated May 25, 2000 from U.S. Rep. Thomas J. Bliley to the HCFA Administrator.

301. Exhibit 1 to U.S. Rep. Pete Stark's September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, reveals that while the AWP for 1 mg of Vincasar® (vincristine sulfate) was \$370.75 in 1997, one physician group's (American Oncology Resources) price in 1997 was only \$4.15. Similarly, while the AWP for 2 mg of Vincasar® was \$741.50, AOR's actual pre-April 1997 price was \$7.75 (in fact, The Pharmacia Group had offered to reduce it to \$7.50).

302. In a letter dated October 3, 2000 to Pharmacia (with accompanying exhibits), Representative Stark addressed the Pharmacia Group's illegal practices:

- a. The manipulated disparities between your company's reported AWPs and DPs are staggering. For example, in 1997, Pharmacia & Upjohn reported an AWP of \$946.94 for 200 mg. of Adriamycin PFS while offering to sell it to American Oncology Resources (AOR) for \$168.00 and to Comprehensive Cancer Center for \$152.00 (Composite Exhibit "1"). Your company then aggressively marketed its cancer drugs to health care providers by touting financial inducements and other types of incentives. Pharmacia & Upjohn created and marketed the financial inducements for the express purpose of influencing the professional judgment of doctors and other health care providers in order to increase the company's market share.
- b. Pharmacia & Upjohn's own internal documents . . . reveal that the company abused its position as a drug innovator

in an initial *Phase III* FDA clinical trial for a cancer drug used to treat lymphoma (Composite Exhibit "2") (emphasis in original).

"... Clinical Research Trials

Initial Phase III Protocol trial for "oral Idamycin" in lymphomas. This trial will offer AOR \$1.1M [million] in additional revenues. Two hundred twenty-five (225) patients at \$5,000 per patient . . . (emphasis added by Rep. Stark)

The above . . . items are contingent on the signing of the AOR Disease Management Partner Program. AOR's exclusive compliance to the purchase of the products listed in the contract product attachment is also necessary for the above items to be in effect."

The linking of doctor participation in FDA clinical drug trials to their purchase and administration of profit-generating oncology drugs is entirely inconsistent with the objective scientific testing that is essential to the integrity of the trial.

- c. It is clear that Pharmacia & Upjohn targeted health care providers, who might be potential purchasers, by creating and then touting the windfall profits arising from the price manipulation. For example, Pharmacia & Upjohn routinely reported inflated average wholesale prices for its cancer drug Bleomycin, 15u, as well as direct prices. The actual prices paid by industry insiders was in many years less than half of what Pharmacia & Upjohn represented. Pharmacia & Upjohn reported that the average wholesale price for Bleomycin, 15u, rose from \$292.43 to \$309.98, while the price charged to industry insiders fell by \$43.15 (Composite Exhibit "4").
- d. Pharmacia & Upjohn reported price increases in October of 1997 with full knowledge that the true prices of the drugs were falling. For example, Composite Exhibit "7" reveals that Pharmacia & Upjohn voluntarily lowered its price of Adriamycin PFS 200 mg to \$152.00 while reporting an AWP of \$946.94:

"Dear Willie,

A (VPR) Voluntary Price Reduction will become effective May 9, 1997. The wholesalers have been notified, however it may take two weeks to complete the transition . . ."

- e. Additionally, internal Pharmacia & Upjohn documents secured through the Congressional investigations show that Pharmacia & Upjohn also utilized a large array of other inducements to stimulate product sales. These inducements, including "educational grants" and free goods, were designed to result in a lower net cost to the purchaser while concealing the actual price beneath a high invoice price. Through these means, drug purchasers were provided substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price – the price that corresponded to reported AWPs and inflated reimbursements from the government. Composite Exhibit "8" highlights these inducements:

AOR/PHARMACIA & UPJOHN PARTNERSHIP PROPOSAL: Medical Education Grants. A \$55,000 grant has been committed for 1997 for the AOR Partnership for excellence package including Education/disease Management, Research Task Force, AOR Annual Yearbook. A \$40,000 grant to sponsor the AOR monthly teleconference. This sponsorship was committed and complete in February 1997 . . .

PHARMACIA & UPJOHN, INC. INTEROFFICE MEMO:

If needed, you have a "free goods" program to support your efforts against other forms of generic doxorubicin . . Use your "free goods" wisely to compete against other generic forms of Adriamycin, not to shift the customer to direct shipments. The higher we can keep the price of Adriamycin, the easier it is for you to meet your sales goals for Adriamycin (emphasis added by Rep. Stark).

303. Pharmacia's marketing pitches, as quoted by U.S. Rep. Pete Stark in a September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, promoted a physician's ability to profit at the expense of Medicare and its beneficiaries:

PHARMACIA: Some of the drugs on the multi-source list offer you savings of over 75% below list price of the drug. For a drug like Adriamycin, the reduced pricing offers AOR a reimbursement of over \$8,000,000 profit when reimbursed at AWP. The spread from acquisition cost to reimbursement on the multi-source products offered on the contract give AOR a wide margin for profit.

304. The government investigators also uncovered an October 3, 1996 internal memorandum wherein Pharmacia told three oncology sales representatives:

Our competitive intelligence tells us that our pricing on Adriamycin, although higher than generics, is in the "ball park" for you to attain the customers' Adriamycin business. If needed, you have a "free goods" program to support your efforts against other forms of generic doxorubicin.

....

You should not have to use "free goods" to steer customer [sic] away from NSS or OTN. OTN and NSS Adriamycin pricing is competitive. Use your "free goods" wisely to compete against other generic forms of Adriamycin, not to shift the customer to direct shipments. The higher we can keep the price of Adriamycin, the easier it is for you to meet your sales goals for Adriamycin.

305. The government's investigation has uncovered substantial evidence that the Pharmacia Group's fraudulent practices are widespread. For example, in a report published by the DHHS, the DOJ documented at least 43 instances where the published AWPs for drugs manufactured by the Pharmacia Group were substantially higher than the actual prices listed by wholesalers.

306. The chart below sets forth 12 drugs for which the Pharmacia Group reported inflated AWPs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the Pharmacia Group.

Drug	The Pharmacia Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Spread
Amphotericin B	\$36.26	\$16.00	\$20.26	127%
Bleomycin Sulfate	\$309.98 ¹⁰	\$158.67	\$151.31	96%
Clindamycin Phosphate	\$93.60	\$61.20	\$32.40	53%
Cyclophosphamide	\$6.29	\$3.92	\$2.37	60%

¹⁰ Calculation based on the AWP listed in the 2000 *Red Book*.

Cytarabine	\$8.98	\$4.06	\$4.92	122%
Doxorubicin HCL	\$1104.13	\$150.86	\$953.27	632%
Etoposide	\$157.65	\$9.47	\$148.18	1,565%
<i>Fluorouracil</i>	\$3.20	\$1.47	\$1.73	118%
Hydrocortisone Sodium Succinate	\$2.00	\$1.55	\$.45	29%
Metholprednisolone Sodium Succinate	\$2.05	\$1.45	\$.60	41%
Testosterone Cypionate	\$17.01	\$11.79	\$5.22	44%
Vincristine Sulfate	\$43.23	\$5.10	\$38.13	748%

307. In OIG report OEI-03-00-00310, the government noted that 20 mg of irinotecan, which according to the *Red Book* is manufactured only by the Pharmacia Group, had a Medicare Median of \$117.81 and a Catalog Median of \$98.63, resulting in a spread of 19.45%.

308. The GAO issued a report entitled "Payments for Covered Outpatient Drugs Exceed Providers' Cost" (GAO-01-1118) wherein it found that irinotecan had an Average AWP of \$141.32, the Average Widely Available Discount from AWP to physicians for irinotecan was 22.9%, and the drug constituted 2.0% of the total amount of Medicare spending in 1999.

309. As of April 2000, another Pharmacia Group drug, Toposar® (etoposide), had an AWP of \$28.38. The DOJ found that retailers were buying it for \$1.70.

310. In 1997, Pharmacia sent to a clinic a proposal listing the AWP and the contract price at which several drugs would be sold to the provider. The differences are staggering and just a few are noted below:

	AWP	Suggested New Contract Price
Adriamycin (10 mg)	46.00	7.50
Adriamycin (50 mg)	230.00	37.50

Neosar (2 g)	86.00	18.00
Toposar (1 g)	1,330.75	120.00
Vincasar (2 mg)	741.50	7.50

311. As set forth above, the Pharmacia Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

P. The Schering-Plough Group (Schering-Plough and Warrick)

312. The Schering-Plough Group has engaged in an ongoing deliberate scheme to inflate AWPs. As stated in a May 4, 2000, letter from U.S. Rep. Tom Bliley, Chairman of the Congressional Committee on Commerce, to Raman Kapur, President of Warrick:

I am writing to you because one of the drugs reflecting a significant variation between the AWP-based prices paid by Medicare and the prices generally charged to private sector purchasers is albuterol sulfate, a drug manufactured by Warrick Pharmaceuticals.

313. In his May 4, 2000, letter, Bliley outlined The Schering-Plough Group's scheme with respect to the prescription drug albuterol sulfate. The government's investigation uncovered a significant spread between the amount Medicare reimbursed for albuterol sulfate and the amount the Schering-Plough Group actually charged. U.S. Rep. Bliley stated:

The OIG [Office of the Inspector General] has determined that the Medicare-allowed amount for albuterol sulfate, a pharmaceutical product sold by your company, in the Fiscal Year 1996 was \$.42. The OIG further estimated that the actual wholesale price of this drug was \$.15 and the highest available wholesale price that the OIG was able to identify was \$.21.

314. In a report to Congress, the GAO reported that albuterol sulfate was one of a small number of products that accounted for the majority of Medicare spending and volume. Albuterol sulfate accounted for 6.3% of total Medicare spending, ranking fifth out of more than 400 covered drugs. Albuterol sulfate ranked first for volume of units covered, accounting for 65.8% of total units reimbursed. *See GAO Report to Congressional Committees, MEDICARE:*

Payments for Covered Outpatient Drugs Exceed Providers' Cost, Tables 1 and 2, pp. 7-8. The Schering-Plough Group is one of three companies noted by the DOJ as manufacturing albuterol. *See Program Memorandum Intermediaries/Carriers*, Sept. 8, 2000, Dept. of Health and Human Serv., Health Care Financing Admin.

315. A Medicaid investigation by the Texas Attorney General revealed that The Schering-Plough Group defrauded the State of Texas \$14.5 million. Investigators determined that The Schering-Plough Group provided the greatest "spread" amongst the drug companies selling albuterol in Texas, and thereby obtained the largest market share for albuterol. The Schering-Plough Group sold a box of albuterol to pharmacies for \$13.50, while it charged the Texas Medicaid program \$40.30, a 200% increase. *See Cornyn Sues Three Drug Companies for Medicaid Fraud*, Press Release by the Office of the Attorney General, State of Texas, Sept. 7, 2000.

316. On October 11, 2001, the West Virginia Attorney General filed suit against Warrick, alleging that Warrick defrauded state agencies and citizens by deliberately overstating the AWP for certain drugs, including albuterol, from approximately 1995 until December 2000.

317. The government's investigation has uncovered substantial evidence that the Schering-Plough Group's fraudulent practices are widespread. For example, in a report published by the DHHS, the DOJ documented at least one instance where the published AWP for a drug manufactured by the Schering-Plough Group was substantially higher than the actual price listed by wholesalers. The Schering-Plough Group reported to *Red Book* an AWP of \$30.25 for albuterol sulfate, yet the DOJ determined the actual AWP to be \$9.16, or \$21.09 less.

318. As set forth above, the Schering-Plough Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

Q. The Sicor Group (Sicor, Gensia and Gensia-Sicor)

319. The Sicor Group has engaged in an ongoing deliberate scheme to inflate AWPs. For example, by letter dated September 25, 2000 to the HCFA administrator, the Chairman of the Commerce Committee revealed that:

[I]n 1998, a health care provider could buy Gensia's Etoposide for \$14.00, while the AWP used to determine Medicare reimbursement was \$141.97.

320. The Sicor Group's marketing strategies further demonstrate its fraudulent practices. In a marketing document prepared by Gensia and obtained by the government in its investigation, Gensia stated:

Concentrate field reps. on the top 40 AIDS hospitals using a \$54.00 price in conjunction with a 10% free goods program to mask final price. Provides the account with an effective price of \$48.60 per vial.

See letter dated September 28, 2000 from U.S. Rep. Pete Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America.

321. Certain handwritten notations appear on this same marketing document comparing the AWP with other prices used for the same drug:

FSS	\$44.95
Whls	\$71.00
Distr.	\$51.50
AWP	\$109.20

322. The government's investigation has uncovered substantial evidence that the Sicor Group's fraudulent practices are widespread. For example, in a report published by the DHHS, the DOJ documented at least 17 instances where the published AWPs for drugs manufactured by The Sicor Group were substantially higher than the actual prices listed by wholesalers.

323. The chart below sets forth three examples of the Sicor Group reporting inflated AWPs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by The Sicor Group in the 2001 *Red Book*.

Drug	The Sicor Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Spread
Acyclovir Sodium	\$125.00 ¹¹	\$100.00	\$25.00	25%
Amikacin Sulfate	\$87.50	\$72.68	\$14.82	20%
Tobramycin Sulfate	\$342.19	\$6.98	\$335.21	4,802%

324. As set forth above, the Sicor Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

R. Watson

325. Watson has engaged in an ongoing deliberate scheme to inflate AWPs in order to increase the market share of its products. Although each of the Medicare Part B reimbursable drugs marketed by Watson is also available from other pharmaceutical manufacturers and are not brand name pharmaceuticals, the government's investigation has uncovered substantial evidence of Watson's fraudulent pricing practices with respect to certain generic pharmaceuticals.

326. Watson's AWP scheme is widespread, and the government investigation has documented substantially inflated AWPs associated with Watson. For example, in a report published by DHHS, the DOJ documented at least 12 instances where the published AWPs pharmaceuticals manufactured and marketed by Watson were substantially higher than the actual prices listed by wholesalers.

327. The chart below sets forth 7 examples of Watson reporting inflated AWPs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the Watson in the 1999-2001 *Red Book*.

¹¹ Calculation based on the AWP listed in the 2000 *Red Book*.

Drug	Watson's 1998-2001 <i>Red Book</i> AWPs	DOJ Determined Actual AWP	Difference	Spread
Dexamethasone Acetate	\$46.45 (1998)	\$11.50	\$34.95	304%
Dexamethasone Sodium Phosphate	\$93.04 (2001)	\$1.08	\$91.96	851%
Diazepam	\$18.15 (2000)	\$2.50	\$15.65	626%
Gentamicin Sulfate	\$114.10 (1999)	\$1.18	\$112.92	957%
Iron Dextran	\$377.04 (2001)	\$24.69	\$352.35	1,427%
Testosterone Ethanate	\$42.10 (2001)	\$13.39	\$28.71	214%
Vancomycin HCL	\$70.00 (1998)	\$3.84	\$60.16	1,567%

328. As set forth above, Watson's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

VI. DIRECT DAMAGE SUSTAINED BY PLAINTIFFS AND THE MEMBERS OF THE CLASS

329. Plaintiffs are directly damaged by Defendants' fraudulent AWP pricing schemes because Plaintiffs frequently are required to make a co-payment for a Covered Drug or a brand name drug, or because such Plaintiffs occasionally make payment in full, and their payments are based on inflated AWPs.

330. For example, as alleged in this Complaint, Medicare Part B recipients must pay 20% of the total amount that is reimbursed by Medicare to the pharmaceutical manufacturer. Thus, if Medicare reimburses \$100 for a covered drug based upon the reported AWP, the Medicare beneficiary is responsible for 20%, or \$20 in the illustrated situation.

331. Many Medicare beneficiaries obtain supplemental insurance known, for example, as "Medigap" or "Medicare Plus" to cover the costs of pharmaceuticals as well as other costs not paid by Medicare. Such supplemental insurers are also Third-Party Payors who are damaged by the AWP Schemes.

332. Plaintiffs and other Third-Party Payors also typically make reimbursement to health care providers for pharmaceuticals based upon the AWP. Accordingly, Third-Party

Payors are directly damaged by fraudulent AWP pricing schemes for drugs covered by employee health and benefit plans or by private insurance because reimbursement is also typically based on the AWP, as in the case of Medicare and Medicaid reimbursement.

VII. CLASS ACTION ALLEGATIONS

333. The Plaintiffs bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of themselves and two Classes comprised of:

Class 1: The Medicare Part B Co-Pay Class:

All persons or entities who, for purposes other than resale and during the Class Period, paid for the purchase of a prescription drug manufactured by a Defendant Drug Manufacturer, which payment constituted a contribution toward the Medicare Part B co-payment.

Class 2: The Third-Party Payor Class:

All Third-Party Payors that, during the Class Period, contracted with a PBM or other intermediary to, based on a "discount" off of AWP, provide to its participants a brand name prescription drug manufactured by a Defendant Drug Manufacturer.

Excluded from the Class are (a) each Defendant and any entity in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors; (b) any co-conspirators; and (c) any governmental entities who purchased such drugs during the Class Period.

334. The Class Period is January 1, 1991 to the present.

335. The Class consists of numerous individuals and entities throughout the United States, making individual joinder impractical, in satisfaction of Rule 23(a)(1). The disposition of the claims of the Class Members in a single class action will provide substantial benefits to all parties and to the Court.

336. The claims of the representative Plaintiffs are typical of the claims of the Class, as required by Rule 23(a)(3), in that the representative Plaintiffs include people and entities who, like all Class Members, purchased the Covered Drugs and/or brand name drugs at inflated

prices based on AWPs. Such representative Plaintiffs, like all Class Members, have been damaged by Defendants' misconduct because, among other things, they paid prices for these drugs that were higher than they would have been but for Defendants' improper actions and, in the case of co-payments, have had medical providers make pharmacy decisions based on economic factors as opposed to purely medical factors.

337. The Class representatives for Class 1, the Medicare Part B Co-Pay Class, are: Plaintiffs Geller, Townsend, Sicher, Lee, Bennett, Munic, Miles, Douglas, Aierstuck, Hudson, Robinson, and the non-profit associations identified in paragraphs 29-51 herein.

338. The Class representatives for Class 2, the Third-Party Payor Class, are: Plaintiffs CMHU, THWF, TCBW, and UFCW Care identified in paragraphs 24-27 herein.

339. The factual and legal bases of each Defendant's misconduct are common to the Class Members and represent a common thread of fraud and other misconduct resulting in injury to Plaintiffs and members of the Class.

340. There are many questions of law and fact common to Plaintiffs and the Class, and those questions predominate over any questions that may affect individual Class Members, within the meaning of and fulfilling Rules 23(a)(2) and 23(b)(3). Common questions of law and fact include, but are not limited to, the following:

- a. Whether Defendants engaged in a fraudulent and/or deceptive scheme of improperly inflating the AWPs for the Covered Drugs and brand name drugs used by Plaintiffs and Class Members as the basis for reimbursement;
- b. Whether Defendants artificially inflated the AWPs for these drugs;
- c. Whether it was the policy and practice of Defendants to prepare marketing and sales materials that contained comparisons of the published AWPs and the spreads available;

d. Whether Defendants provided free samples of the Covered Drugs to providers, and whether Defendants instructed them to bill Plaintiffs and the Class for those free samples;

e. Whether Defendants' provision of free samples to providers, with the intent that the providers bill Plaintiffs and the Class for the free samples, was unlawful;

f. Whether Defendants paid financial inducements to providers and other intermediaries, with the effect of lowering their costs for Covered Drugs and brand name drugs;

g. Whether Defendants engaged in a pattern and practice of paying illegal kickbacks, disguised as free goods, rebates, consulting fees, junkets and education grants to providers and other intermediaries;

h. Whether Defendants engaged in a pattern and practice that caused Plaintiffs and Class Members to make inflated payments for the Covered Drugs and brand name drugs;

i. Whether Defendants engaged in a pattern of deceptive and/or fraudulent activity intended to defraud Plaintiffs and the Class members;

j. Whether Defendants formed enterprises for the purpose of carrying out the AWP Scheme;

k. Whether Defendants used the U.S. mails and interstate wire facilities to carry out the AWP Scheme;

l. Whether Defendants' conduct violated RICO;

m. Whether AWPs are used as a benchmark for negotiating payments by Third-Party Payors for brand name drugs;

n. Whether Defendants are liable to Plaintiffs and the Class members for damages for conduct actionable under the various state consumer protection statutes.

341. Plaintiffs will fairly and adequately represent and protect the interests of the Class, as required by Rule 23(a)(4). Plaintiffs have retained counsel with substantial

experience in prosecuting nationwide consumer class actions. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the Class, and have the financial resources to do so. Neither Plaintiffs nor their counsel have any interest adverse to those of the Class.

342. Plaintiffs and members of the Class have all suffered, and will continue to suffer, harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of this controversy under Rule 23(b)(3). Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the Courts and the litigants, and promotes consistency and efficiency of adjudication. Additionally, Defendants have acted and failed to act on grounds generally applicable to Plaintiffs and the Class and require Court imposition of uniform relief to ensure compatible standards of conduct toward the Class, thereby making appropriate equitable relief to the Class as a whole within the meaning of Rules 23(b)(1) and (b)(2).

COUNT I

VIOLATIONS OF 18 U.S.C. § 1962(c)-(d)

**(AGAINST DEFENDANT DRUG MANUFACTURERS FOR UNLAWFUL CONDUCT
ASSOCIATED WITH MEDICARE PART B COVERED DRUGS)**

343. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint.

344. This Count, which alleges violations of Sections 1962(c) and (d) of RICO, 18 U.S.C. §§ 1962(c)-(d), is asserted against the Defendant Drug Manufacturers and is brought on behalf of Class 1 by the Class 1 representatives.

345. Plaintiffs, the members of Class 1, the Defendant Drug Manufacturers and the providers are each “persons,” as that term is defined in 18 U.S.C. § 1961(3). At all relevant times, in violation of 18 U.S.C. § 1962(c), the Defendant Drug Manufacturers each conducted the affairs of certain association-in-fact enterprises identified herein, the affairs of which affected interstate commerce through a pattern of racketeering activity.

The AWP Enterprises

346. In accordance with 18 U.S.C. § 1961(4), the RICO “enterprises” enumerated in ¶ 350(a)-(u) of this Complaint are associations-in-fact consisting of (a) various and independent medical providers who prescribed Covered Drugs for which a Defendant Drug Manufacturer reported an AWP, and (b) a Defendant Drug Manufacturer, including its directors, employees, and agents (“the AWP Enterprises”). The AWP Enterprises are ongoing and continuing business organizations consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to Plaintiffs and Class 1 members who are individual persons, and to participants in those Plaintiffs and Class 1 members who comprise health and welfare plans, and deriving profits from these activities.

347. The providers are alleged to be members of the AWP Enterprises because they were integral participants in the Defendant Drug Manufacturers’ AWP Scheme. Indeed, the providers were the parties who actually sought reimbursement from Plaintiffs and the members of Class 1.

348. The providers were aware of the Defendant Drug Manufacturers’ scheme, were knowing and willing participants in the AWP Scheme, and were aware of the involvement of other similarly-situated providers in that fraudulent and unlawful scheme.

349. The Defendant Drug Manufacturers and the providers operated collectively, pursuant to a conspiratorial agreement, a common purpose and as a continuing unit, to perpetrate the fraudulent AWP Scheme relating to the Covered Drugs alleged herein and their

collective knowledge, wrongful activity and willing involvement in the Defendant Drug Manufacturers' AWP Scheme is evidenced by:

- (a) The mass market nature of the various promotional and sales material created and communicated by Defendant Drug Manufacturers to providers. Such pre-printed materials were obviously designed for a mass audience and not just for a single provider;
- (b) The attendance by many providers at meetings of professional organizations, at which Defendant Drug Manufacturers established booths and exhibits discussing the wrongful practices alleged herein, including the "spread" and "return to practice,"
- (c) The failure of any providers to advise U.S. Government regulators (including Medicare), private insurers and patients, including Plaintiffs and the members of Class 1, of the existence of the spreads;
- (d) The fact that each provider was aware that he, she or it was making a profit from the spread, based on the nationally-published AWPs; and
- (e) The fact that various provider professional organizations aggressively lobbied against any change away from reimbursement for these Covered Drugs based upon AWPs.

350. The AWP Enterprises are identified as follows:

- (a) *The Abbott Provider Enterprise:* The Abbott Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Abbott reported an AWP, and Defendant Abbott, including its directors, employees and agents. The Abbott Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and

Class 1 members, and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Abbott Provider Enterprise affected interstate commerce.

(b) *The Amgen Provider Enterprise:* The Amgen Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Amgen reported an AWP, and Defendant Amgen, including its directors, employees and agents. The Amgen Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and the Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Amgen Provider Enterprise affected interstate commerce.

(c) *The AstraZeneca Provider Enterprise:* The AstraZeneca Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which AstraZeneca reported an AWP, and AstraZeneca, including its directors, employees and agents. The AstraZeneca Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the AstraZeneca Provider Enterprise affected interstate commerce.

(d) *The Aventis Group Provider Enterprise:* The Aventis Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the Aventis Group reported an AWP, and the Aventis Group, including its directors, employees and agents. The Aventis Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Aventis Group Provider Enterprise affected interstate commerce.

(e) *The Baxter Provider Enterprise:* The Baxter Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Baxter reported an AWP, and Baxter, including its directors, employees and agents. The Baxter Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Baxter Provider Enterprise affected interstate commerce.

(f) *The Bayer Provider Enterprise:* The Bayer Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Bayer reported an AWP on the one hand, and Bayer, including its directors, employees and agents. The Bayer Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and

individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Bayer Provider Enterprise affected interstate commerce.

(g) *The Boehringer Group Provider Enterprise:* The Boehringer Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the Boehringer Group reported an AWP, and the Boehringer Group, including its directors, employees and agents. The Boehringer Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Boehringer Group Provider Enterprise affected interstate commerce.

(h) *The Braun Provider Enterprise:* The Braun Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Braun reported an AWP, and Braun, including its directors, employees and agents. The Braun Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise

health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Braun Provider Enterprise affected interstate commerce.

(i) *The BMS Group Provider Enterprise:* The BMS Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the BMS Group reported an AWP, and the BMS Group, including its directors, employees and agents. The BMS Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the BMS Group Provider Enterprise affected interstate commerce.

(j) *The Dey Provider Enterprise:* The Dey Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Dey reported an AWP, and Dey, including its directors, employees and agents. The Dey Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Dey Provider Enterprise affected interstate commerce.

(k) *The Fujisawa Group Provider Enterprise:* The Fujisawa Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the Fujisawa Group reported an

AWP, and the Fujisawa Group, including its directors, employees and agents. The Fujisawa Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Fujisawa Group Provider Enterprise affected interstate commerce.

(l) *The GSK Group Provider Enterprise:* The GSK Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the GSK Group reported an AWP, and the GSK Group, including its directors, employees and agents. The GSK Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the GSK Group Provider Enterprise affected interstate commerce.

(m) *The Hoffman-La Roche Provider Enterprise:* The Hoffman-La Roche Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Hoffman-La Roche reported an AWP, and Hoffman-La Roche, including its directors, employees and agents. The Hoffman-La Roche Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and

administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Hoffman-La Roche Provider Enterprise affected interstate commerce.

(n) *The Immunex Provider Enterprise:* The Immunex Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Immunex reported an AWP, and Immunex, including its directors, employees and agents. The Immunex Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Immunex Provider Enterprise affected interstate commerce.

(o) *The Johnson & Johnson Group Provider Enterprise:* The Johnson & Johnson Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the Johnson & Johnson Group reported an AWP, and the Johnson & Johnson Group, including its directors, employees and agents. The Johnson & Johnson Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these

activities. At all relevant times hereto, the activities of the Johnson & Johnson Group Provider Enterprise affected interstate commerce.

(p) *The Merck Provider Enterprise:* The Merck Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Merck reported an AWP, and Merck, including its directors, employees and agents. The Merck Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Merck Provider Enterprise affected interstate commerce.

(q) *The Pfizer Provider Enterprise:* The Pfizer Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Pfizer reported an AWP, and Pfizer, including its directors, employees and agents. The Pfizer Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Pfizer Provider Enterprise affected interstate commerce.

(r) *The Pharmacia Group Provider Enterprise:* The Pharmacia Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the Pharmacia Group reported an AWP, and the Pharmacia Group, including its directors, employees and